

Food and Drug Administration, HHS

§ 201.61

Effective	Revised labeling due	Drug class	Mail routing code
Dodo	Antitussives	HFD-160
Dodo	Expectorants	Do.
Dodo	Inhalants	Do.
June 1, 1984 ..	June 1, 1982 ..	Urinary tract antiseptics	HFD-520
July 1, 1984 ..	July 1, 1982 ..	Chelating agents/heavy metal antagonists	HFD-110
Dodo	All other gastrointestinal drugs	HFD-110
Dodo	Antianxiety	HFD-120
Dodo	Drugs indicated for myasthenia gravis	HFD-120
Dodo	All other antiinfective drugs	HFD-520
Dodo	Bronchodilators/antiasthmatics	HFD-160
Aug. 1, 1984 ..	Aug. 1, 1982 ..	Estrogens	HFD-510
Dodo	Uterine stimulants	HFD-510
Dodo	Uterine relaxants	Do.
Sept. 1, 1984 ..	Sept. 1, 1982 ..	Drugs indicated for hypotension and shock	HFD-110
Oct. 1, 1984 ..	Oct. 1, 1982 ..	All other cardiac drugs	HFD-110
Dodo	Nasal decongestants	HFD-160
Nov. 1, 1984 ..	Nov. 1, 1982 ..	All other prescription drugs.	

¹ Except the effective date for all biological products reviewed generically by the advisory panel is 30 months after a final order is published under 21 CFR 601.25(g).

² Except the due date for all biological products reviewed generically by the advisory panel is 6 months after a final order is published under 21 CFR 601.25(g).

(b) Section 201.100(e) is effective April 10, 1981.

[45 FR 32552, May 16, 1980, as amended at 46 FR 7272, Jan. 23, 1981; 49 FR 14331, Apr. 11, 1984; 50 FR 8995, Mar. 6, 1985; 55 FR 11576, Mar. 29, 1990; 64 FR 400, Jan. 5, 1999]

Subpart C—Labeling Requirements for Over-the-Counter Drugs

SOURCE: 41 FR 6908, Feb. 13, 1976, unless otherwise noted.

§ 201.60 Principal display panel.

The term *principal display panel*, as it applies to over-the-counter drugs in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring designs, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term *area of the prin-*

cipal display panel means the area of the side or surface that bears the principal display panel, which area shall be:

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference; and

(c) In the case of any other shape of container, 40 percent of the total surface of the container: *Provided, however*, That where such container presents an obvious “principal display panel” such as the top of a triangular or circular package, the area shall consist of the entire top surface.

In determining the area of the principal display panel, exclude tops, bottoms, flanges at the tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

§ 201.61 Statement of identity.

(a) The principal display panel of an over-the-counter drug in package form